PB87-115622

Pesticide Fact Sheet Number 42: Vitamin D3

(U.S.) Environmental Protection Agency
Washington, DC

1 Dec 84

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE | 1. REPORT NO. | 2. | 3. Recipient's Accession No. PB87-115622/AS

4. Title and Subtitle: EPA Pesticide Fact Sheets - VITAMIN D-3 No. 42

5. Report Date: Issued 12/1/84

6.

7. Author(s): EPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No. 540/FS-87- 073

9. Performing Organization Name and Address:
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10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address:
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, Science Findings

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available

19. Security Class (This Report): Unclassified

20. Security Class (This Page): Unclassified

21. No. of Pages: 4

22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-788C)
Washington, DC 20460

PB87-115622

EPA Pesticide Fact Sheet

Name of Chemical: VITAMIN D_3
Reason for Issuance:
Date Issued: December 1, 1984
Fact Sheet Number: 42

1. Description of chemical:

Generic name: Cholecalciferol, Activated 7-dehydrocholesterol, oleovitamin D_3, 9,10-secocholesta-5,7,10(19)-trien-3B-ol [NEW CHEMICAL]
Common name:
Trade name: Vitamin D_3
EPA Shaughessy code: 208700
Chemical Abstracts Service (CAS) number: 434-16-2
Year of initial registration: 1984
Pesticide type: rodenticide
Chemical family: sterol
U.S. and foreign producers: Phillips-Duphar (Netherlands)
Active ingredient
Bell Laboratories (Madison, WI)
Formulated product

2. Use patterns and formulations:

Application sites: in and around buildings, inside of transport vehicles
Pest species: norway rats, roof rats, and house mice
Type of formulations: granular (0.075% bait)
Type and method of application: topical, hand application
Application rates: 2-8 oz./15-30 ft. (rats)
1/4-1 oz./8-12ft. (mice)
Usual carriers: Confidential Business Information

3. Science findings:

Summary science statement:

Adequate studies are available to assess the acute toxicological hazards of technical and formulated Vitamin D_3. No toxicological hazards of concern were identified. Available studies indicate that Vitamin D_3 is of low toxicity to birds; studies on fish are inapplicable because Vitamin D_3 is virtually insoluble in water. The registration of this new active ingredient is conditioned on submittal of additional efficacy data by January 1976.

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Chemical characteristics:

Technical Vitamin D_3 is a solid resin. The empirical formula is $C_{27}H_{44}O$, and the molecular weight is 384.62. The melting point is is 84-85°C. Vitamin D_3 is practically soluble in water, soluble in the usual organic solvents, and slightly soluble in vegetable oils.

Toxicological characteristics:

Currently available toxicology studies on Vitamin D_3 are as follows:

- Oral LD_{50} in rats: 352 mg/kg and 42 mg/kg for males and 619 mg/kg for females.
- Dermal LD_{50} in rabbits: >2000 mg/kg.
- Primary dermal irritation: not required because technical is a solid resin.
- Primary eye irritation: not required because technical is a solid resin.
- Inhalation LC_{50}: not required because technical is a solid resin.
- Acute, 60-day, Delayed Toxicity Study in rats: Acute dose, equal to accidental exposure, produced no elevated serum calcium levels and no abnormal long bone growth in young rats.
- Teratology in rats: not required because technical is a solid resin and Vitamin D_3, is a dietary supplement in the adult female diet.

Adequate studies are available to assess the acute toxicological effects of Vitamin D_3. No toxicological hazards of concern have been identified in the studies reviewed for this new pesticide.

Physiological and biochemical behavioral characteristics:

The registrant submitted a volume on the metabolism and function of Vitamin D_3. However, because Vitamin D_3 is a non-food use, is applied topically, and in small amounts, we did not review this submission of such imformation.

Environmental characteristics:

Because of the use pattern of this chemical (in and around buildings and inside of transport vehicles, we did not request any enviornmenal fate data.

Ecological characteristics:

Based on studies available to assess hazards to wildlife and aquatic organisms, Vitamin D_3 is characterized as being of low toxicity to birds. Because the chemical is virtually insoluable in water, we requested no aquatic toxicity data.

Results of currently available studies are as follows:

- avian oral LD_{50}: >2000 mg/kg (mallard duck)
- avian dietary LC_{50}: 4000 ppm (mallard duck)
  2000 ppm (bobwhite quail)
- fish LC_{50}: not required because technical is virtually insoluable in water.
- aquatic invertebrate LC_{50}: not required because technical is virtually insoluable in water.

Product Performance characteristics:

Because the Agency had suspended the efficacy requirements for this type of product, the company did not complete all the pre-suspension data. Subsequently, the Agency notified the company that it had re-instituted these data. The company will have a reasonable period of time (until January 1, 1986) to supply the missing laboratory and field data.

4. Summary of regulatory position and rationale:

The Agency has placed the one registered formulation in Toxicity Category III (CAUTION) and has classified this use pattern (in and around buildings and inside of transport vehicles for norway rats, roofs rats, and house mice) as "Unclassified". Such a product can be sold over-the-counter. The Agency has not identified a potential for adverse effects for man or the environment, based on the submitted toxicology and fish and wildlife data. Because of re-institution of the efficacy data requirements, the registration will be conditioned on the submittal of additional, acceptable laboratory and field efficacy data within fourteen months.

5. Summary of major data gaps:

-LD-50 tests on target species
-Laboratory, choice-test, efficacy data for target species
-Field efficacy data

All studies are to be submitted to the Agency by January 1, 1986.

6. Contact Person at EPA

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